USSN 10/699,586
Group Art Unit: 3739
Docket No. 151-P-11200US01

REMARKS

Claims 1, 6 – 9 and 13 – 15 are pending in this application.

Claims 1 – 15 have been rejected.

Amendments to the Claims

Claims 2 – 5 and 10 – 12 have been canceled.

Independent claims 1 and 9 have been amended.

Independent claim 1 has been amended to incorporate the subject matter roughly equal to prior claim 2 (hemispherical shape) and prior claim 4 (hemispherical shape approximately equal to first predetermined diameter) and a combination of claims 6 and 7 (first predetermined diameter not greater than second predetermined diameter). Support for this amendment can be found generally in the specification and additionally in the claims in claims 2, 4, 6 and 7. No new matter has been added.

Independent claim 9 has been amended to incorporate the subject of roughly equal to prior claim 10 (hemispherical shape) and prior claim 11 (hemispherical shape approximately equal to first predetermined diameter) and a combination of claims 13 and 14 (first predetermined diameter not greater than second predetermined diameter). Support for this amendment can be found generally in the specification and additionally in the claims in claims 10, 11, 13 and 14. No new matter has been added.

Entry of these amendments to the claims is earnestly solicited in accordance with the procedures of 37 CFR § 1.116 presenting rejected claims in better form for appeal.

Rejections Under 35 USC § 102(e)

Claims 1 – 15 have been rejected under 35 USC § 102(e) as being anticipated by U.S. Patent No. 6,761,718, Madsen ("Madsen '718"). These rejections, over the claims as amended, are respectfully traversed.

Madsen '718

Madsen '718 discloses a bipolar coagulator which can be passed through the internal lumen of a ventricular catheter previously implanted into a cranial ventricle of a living subject and engaged in-situ. The bipolar coagulator will provide bipolar electrical arc currents for coagulation cauterization of adherent brain tissues, such as the choroids plexus, which occludes fluid flow into the intake drainage holes in the implanted ventricular catheter.

The bipolar coagulator has a proximal end adapted to be inserted through the lumen of an already inserted ventricular catheter. The bipolar coagulator has two electrodes intended to coagulate adherent brain tissues, such as the choroids plexus, which otherwise would occlude ports in the sidewall of the catheter. Thus, the sole intended purpose of the bipolar coagulator is to clear ports in an already-inserted in-vivo ventricular catheter.

Apparatus Claims (1 and 6 – 8)

Apparatus claims 1 and 6 – 8 all require an "apparatus for making a hole ... in a dura of a patient for the insertion of a catheter." In contrast, Madsen '718 discloses a bipolar coagulator for coagulating brain tissue, not for making a hole in the dura, in a catheter already inserted in-vivo, not for the insertion of a catheter. Not only does Madsen '718 not disclose an apparatus for making a hole in the dura, the apparatus disclosed in Madsen '718 is not suitable for making a hole in the dura. The electrodes of the bipolar coagulator disclosed in Madsen '718 are located along the side of the proximal portion of the elongated body in order to match with the ports located on the sides of the catheter. So positioned, the electrodes could not effectively make a hole in the dura. Thus, the bipolar coagulator disclosed in Madsen '718 fails to anticipate apparatus claims 1 and 6 – 8 for this reason alone.

In addition, claim 1 has been amended to explicitly require a stylet with a tip having a hemispherical shape and requiring specific structural relationships between the elements, namely that the diameter of the hemispherical shape of the tip of the stylet

being approximately equal the first predetermined diameter (hole in the dura) and that the first predetermined diameter is not greater than the second predetermined diameter (diameter of the catheter).

These specific structural relationships are not shown nor suggested in the disclosure of Madsen '718. Nor does Madsen '718 achieve the significant advantages associated with these structural elements, namely the control of leakage of CSF around a catheter placed through the dura in order to accomplish shunting into the ventricles and/or into the sagittal sinus. Controlling leakage of CSF can improve shunt performance by controlling or eliminating the potential for the serious side effects.

Not only are apparatus claims 1 and 6 – 8 not anticipated, there is no disclosure in Madsen '718 to teach or suggest the claimed structure. Thus, Madsen et al also fails to render apparatus claims 1 and 6 – 8 unpatentable for obviousness.

Thus, apparatus claims 1 and 6 – 8 are believed patentable over Madsen '718, the rejections of claims 1 and 6 – 8 are respectfully believed to erroneous, at least over the claims as amended, and should be withdrawn.

Method Claims 9 and 13 – 15

Method claims 9 and 13 – 15 require a method "for making a hole ... in a dura of a patient ... for the insertion of a catheter." In contrast, Madsen '718 discloses a bipolar coagulator for coagulating brain tissue, not for making a hole in the dura, in a catheter already inserted in-vivo, not for the insertion of a catheter. Not only does Madsen '718 not disclose an apparatus for making a hole in the dura, the apparatus disclosed in Madsen '718 is not suitable for making a hole in the dura. The electrodes of the bipolar coagulator disclosed in Madsen '718 are located along the side of the proximal portion of the elongated body in order to match with the ports located on the sides of the catheter. So positioned, the electrodes could not effectively make a hole in the dura. Thus, the bipolar coagulator disclosed in Madsen '718 fails to anticipate method claims 9 – 15 for this reason alone.

In addition, method claim 9 also requires inserting a stylet having a tip having a hemispherical shape and requiring specific structural relationships between the elements, namely that the diameter of the hemispherical shape of the tip of the stylet being approximately equal the first predetermined diameter (hole in the dura) and that the first predetermined diameter is not greater than the second predetermined diameter (diameter of the catheter).

These specific method steps are not shown nor suggested in the disclosure of Madsen '718. Nor does Madsen '718 achieve the significant advantages associated with these structural elements, namely the control of leakage of CSF around a catheter placed through the dura in order to accomplish shunting into the ventricles and/or into the sagittal sinus. Controlling leakage of CSF can improve shunt performance by controlling or eliminating the potential for the serious side effects.

Not only are method claims 9 and 13 – 15 not anticipated, there is no disclosure in Madsen '718 to teach or suggest such specific method steps. Thus, Madsen et al also fails to render method claims 9 and 13 – 15 unpatentable for obviousness.

Thus, method claims 9 and 13 – 15 are believed patentable over Madsen '718, the rejections of claims 9 and 13 – 15 are respectfully believed to erroneous and should be withdrawn.

Advisory Action

With the submission of this amendment within the two (2) months following the mailing date of the Office Action made FINAL, it is respectfully requested that an advisory action be issued.

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Summary

In view of the amendments made and the arguments presented, claims 1, 6 – 9 and 13 – 15 should be allowable, this application should be in condition for allowance and a notice to that is earnestly solicited.

Respectfully Submitted,

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